



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-N-2143]

#### **Xellia Pharmaceuticals USA, LLC; Withdrawal of Approval of an Abbreviated New Drug Application for Bacitracin for Injection**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration's (FDA or Agency) Center for Drug Evaluation and Research (CDER) is withdrawing the approval of an abbreviated new drug application (ANDA) for bacitracin for injection, 50,000 units/vial (ANDA 203177), held by Xellia Pharmaceuticals USA, LLC (Xellia). Xellia has requested withdrawal of approval of this application and has waived its opportunity for a hearing.

**DATES:** Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**FOR FURTHER INFORMATION CONTACT:** Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993-0002, 301-402-9674, [Sungjoon.Chi@fda.hhs.gov](mailto:Sungjoon.Chi@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On January 31, 2020, FDA requested that all application holders of bacitracin for injection voluntarily request withdrawal of approval of their applications under § 314.150(d) (21 CFR 314.150(d)). Bacitracin for injection is an antibiotic for intramuscular administration, the use of which is limited to the treatment of infants with pneumonia and empyema caused by staphylococci shown to be susceptible to the drug. Bacitracin for injection poses serious risks, including nephrotoxicity and anaphylactic reactions. Health care professionals generally no longer use bacitracin for injection to treat infants with

pneumonia and empyema because other effective FDA-approved treatments are available that do not have these risks.

In April 2019, FDA's Antimicrobial Drugs Advisory Committee met and discussed the safety and effectiveness of bacitracin for injection. The advisory committee voted almost unanimously, with one abstention, that the benefits of bacitracin for intramuscular injection do not outweigh its risks, including nephrotoxicity and anaphylactic reactions, for the drug's only approved indication. Based on FDA's review of currently available data and information, the Agency believes that the potential problems associated with bacitracin for injection are sufficiently serious that the drug should be removed from the market.

In a letter dated June 14, 2021, Xellia requested that FDA withdraw approval of ANDA 203177 under § 314.150(d) and waived its opportunity for a hearing. Therefore, for the reasons discussed above, which the applicant does not dispute in its letter requesting withdrawal of approval under § 314.150(d), FDA's approval of ANDA 203177 and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of Xellia's bacitracin for injection (50,000 units/vial) into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d))).

Dated: July 5, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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